REMARKS

Reconsideration of the present application is requested. Applicants appreciate the withdrawal of the prior rejection based on Applicants' response of October 24, 2008.

Following that response, however, a new ground of rejection was issued using a new reference, U.S. Patent No. 6,716,216 to Boucher et al. It was suggested that Boucher discloses a cannula instrument 84 for flow of fluent material therethrough. The tool 160 (FIG. 22b) was said to correspond to the extent adapted to be received in an annular opening, as recited in independent claim 85. It was further suggested that the gasket 122 constitutes a seal adapted to engage the annulus.

The tool 160 is separate from the cannula instrument 84. Specifically the tool 160 is inserted through the cannula instrument. See, col. 26, ll. 25-56. Thus, the cannula instrument 84 cannot be regarded as "having ... an extent" corresponding to the separate tool 160. The tool 160 is not part of the cannula instrument 84 and therefore cannot be "an extent" of that instrument. Extending from that instrument does not make the tool "an extent" of that instrument.

When the language of claim 85 is properly considered, either the cannula instrument 84 or the tool 160 must meet the limitations of the "tube" recited in claim 85 in order to support the obviousness rejection. If the cannula instrument 84 is considered it is clear that the instrument 84 does not include both a distal tip and a seal, as recited in claim 85. The gasket 122 identified in the office action as the seal is apparently mounted on the distal end of the cannula instrument 84, as depicted in FIG. 16h. The distal end of the cannula instrument therefore must be smaller than the opening through which it extends; otherwise the gasket 122 could not be located as shown in the figure. If the distal end of the cannula instrument 84 is smaller than the opening it cannot be "sized and configured to provide distraction of opposed vertebrae", as required by claim 85. In other words, the cannula instrument 84 in Boucher does not have the ability to distract a disc space.

It is noted that the limitation in claim 85 that the distal tip is "sized and configured to provide distraction" was essentially ignored as not imparting structural limitations. Although it is believed that this language clearly points to structural limitations, Applicants have amended claim 85 to define the distal tip as having a dimension that is

greater than the height of the disc space in which this dimension is sized and configured to provide distraction. The addition of this language even more clearly shows the insufficiency of the Boucher reference, since the distal tip of the cannula instrument is not disclosed as having a dimension greater than the height of the disc space that is sized and configured to distract the space. (It is noted that the instrument 84 has a length that is likely greater than the disc space height, but this length is not configured to distract, as required by the claim because the instrument obviously cannot be introduced into the disc space lengthwise.)

The other alternative in the office action is that the tool 160 corresponds to the tube recited in claim 85. The tool 160 is tapered and it was apparently alleged in the office action that this tapered tool was sized and configured to provide distraction. However, the contrary conclusion is apparent from the Boucher disclosure. The tool 160 is disclosed as passing through the cannula instrument 84. See, col. 26, ll. 25-56. This cannula instrument is shown as extending into the prepared opening. See, FIG. 16h. The cannula instrument is not sized and configured to distract the adjacent vertebrae. Since the tool 160 passed through the inside of the instrument 84, it obviously cannot be larger than the instrument. If it cannot be larger than the instrument 84 then it clearly cannot be sized to distract.

Thus, the tool 160 is not "sized and configured to provide distraction" as required by claim 85. Moreover, the tool 160 does not have a dimension that is greater than the height of the disc space as required by claim 85 as amended.

Significantly, the Boucher patent only discloses the treatment of vertebral bodies, not the intervertebral disc. Thus, there is nothing in Boucher that discloses distracting adjacent vertebrae and there is certainly no suggestion to use the devices in Boucher for treating an intervertebral disc. Moreover, there is nothing in Boucher that discloses or contemplates introducing a device through an opening in the annulus fibrosus. While it may be argued that the discussion of the annular opening and distraction is merely "intended use", the structural language recited in claim 85 cannot be ignored. This structural language relates to the disc space height as well as the distraction of the adjacent vertebrae. Since Boucher is only concerned with treatment of the vertebral body

itself, there is nothing to suggest the significant revisions necessary to meet the limitations of Applicants' claim 85.

It is therefore believed that claim 85 is patentable over Boucher for the reasons just discussed. The allowability of claim 85 inures to the benefit of its dependent claims 81, 82, 83, 84, 86-91 and 93-96. In addition, certain of the dependent claims are patentable on their own merits.

For example, claim 87 defines the distal tip as being removable from the tube. In the office action the tools 120, 160 and 164 were equated with the claimed distal tips. However, as explained above, the tools cannot be the claimed distal tips because the tools are inserted through the cannula instrument. The Boucher reference does not disclose or suggest a distal tip that is "removable from" the tube, as recited in claim 87, or the plurality of such tips, as defined in claim 88.

Dependent claim 89 defines the distal tip as being formed of a bioresorbable material. This limitation was not addressed in the office action, nor is it actually found in the Boucher reference. Moreover, since both the cannula instrument 50 and tool 160 are intended to be removed from the vertebral body there is no reason for either of these components to be formed of a bioresorbable material.

In view of the foregoing arguments and amendment to claim 85, it is believed that the present application is in condition for allowance, including claims 81, 82, 84-91 and 93-96. Action toward a Notice of Allowance is respectfully requested.

Respectfully submitted,

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